

House Amendment 1428

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1 1 Amend House File 833 as follows:
1 2 #1. Page 1, by inserting before line 1 the
1 3 following:
1 4 <Section 1. Section 22.7, Code 2005, is amended by
1 5 adding the following new subsection:
1 6 NEW SUBSECTION. 51. The information contained in
1 7 the electronic drug database established in section
1 8 124.510A, except to the extent that disclosure is
1 9 authorized pursuant to section 124.510C.
1 10 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG
1 11 DATABASE ESTABLISHED.
1 12 The board shall establish and maintain an
1 13 electronic drug database. The board shall use the
1 14 electronic drug database to monitor the misuse, abuse,
1 15 and diversion of selected controlled substances and
1 16 other drugs the board includes in the database
1 17 pursuant to section 124.510E, subsection 1, paragraph
1 18 "i". The board shall electronically collect and
1 19 disseminate information pursuant to sections 124.510C
1 20 and 124.510D and rules adopted pursuant to this
1 21 division. The board may contract with a third=
1 22 party/private vendor to administer the electronic drug
1 23 database.
1 24 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.
1 25 1. Each licensed pharmacy that dispenses selected
1 26 drugs identified by the board by rule to patients in
1 27 the state, and each licensed pharmacy located in the
1 28 state that dispenses such selected drugs to patients
1 29 inside or outside the state, unless specifically
1 30 excepted in this section or by rule, shall submit the
1 31 following prescription information to the board or its
1 32 designee:
1 33 a. Pharmacy identification.
1 34 b. Patient identification.
1 35 c. Prescriber identification.
1 36 d. The date the prescription was issued by the
1 37 prescriber.
1 38 e. The date the prescription was dispensed.
1 39 f. An indication of whether the prescription
1 40 dispensed is new or a refill.
1 41 g. Identification of the drug dispensed.
1 42 h. Quantity of the drug dispensed.
1 43 i. The number of days' supply of the drug
1 44 dispensed.
1 45 j. Serial or prescription number assigned by the
1 46 pharmacy.
1 47 k. Source of payment for the prescription.
1 48 2. Information shall be submitted electronically
1 49 in the format specified by the board unless the board
1 50 has granted a waiver and approved an alternate format.
2 1 3. Information shall be timely transmitted as
2 2 designated by the board by rule, unless the board
2 3 grants an extension. The board may grant an extension
2 4 if either of the following occurs:
2 5 a. The pharmacy suffers a mechanical or electronic
2 6 failure, or cannot meet the deadline established by
2 7 the board for other reasons beyond the pharmacy's
2 8 control.
2 9 b. The board or its designee is unable to receive
2 10 electronic submissions.
2 11 4. This section shall not apply to a prescriber
2 12 furnishing, dispensing, supplying, or administering
2 13 drugs to the prescriber's patient, or to dispensing by
2 14 a licensed pharmacy for the purposes of inpatient
2 15 hospital care, inpatient hospice care, or long-term
2 16 residential facility patient care.
2 17 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.
2 18 1. The board or its designee may provide
2 19 information from the electronic drug database to all
2 20 of the following:
2 21 a. A person who is a designated representative of
2 22 a governmental entity responsible for the licensure,
2 23 regulation, or discipline of licensed health care
2 24 professionals authorized to prescribe or dispense

2 25 drugs, who is involved in an investigation of a person
2 26 licensed, regulated, or subject to discipline by the
2 27 entity, and who is seeking access to information in
2 28 the database that is relevant to the subject matter of
2 29 the investigation and pursuant to a written probable
2 30 cause determination.

2 31 b. A federal, state, county, township, or
2 32 municipal officer of this or any other state, or the
2 33 United States, whose duty it is to enforce the laws
2 34 relating to prescription drugs and who is actively
2 35 engaged in a specific investigation of a specific
2 36 person and is seeking access to information in the
2 37 database pursuant to a probable cause determination or
2 38 warrant.

2 39 c. A properly convened grand jury pursuant to a
2 40 subpoena properly issued.

2 41 d. A pharmacist or prescriber who requests the
2 42 information and certifies in a form specified by the
2 43 board that it is for the purpose of providing medical
2 44 or pharmaceutical care to a patient of the pharmacist
2 45 or prescriber.

2 46 e. An individual who requests the individual's own
2 47 database information in accordance with the procedure
2 48 established in rules of the board adopted under
2 49 section 124.510E.

2 50 2. The board or its designee shall maintain a
3 1 record of each person that requests information from
3 2 the database. Pursuant to rules adopted by the board
3 3 under section 124.510E, the board may use the records
3 4 to document and report statistics and law enforcement
3 5 outcomes and to identify inappropriate access or other
3 6 prohibited acts. The board or its designee may
3 7 provide records of a person's requests for database
3 8 information to the following persons:

3 9 a. Pursuant to a probable cause determination, a
3 10 designated representative of a governmental entity
3 11 that is responsible for the licensure, regulation, or
3 12 discipline of licensed health care professionals
3 13 authorized to prescribe or dispense drugs who is
3 14 involved in a specific investigation of the individual
3 15 who submitted the request.

3 16 b. Pursuant to a probable cause determination or
3 17 warrant, a federal, state, county, township, or
3 18 municipal officer of this or any other state or the
3 19 United States, whose duty is to enforce the laws
3 20 relating to prescription drugs, and who is actively
3 21 engaged in a specific investigation of the specific
3 22 person who submitted the request.

3 23 3. Information contained in the database and any
3 24 information obtained from it is strictly confidential
3 25 medical information, is not a public record pursuant
3 26 to chapter 22, and is not subject to discovery,
3 27 subpoena, or other means of legal compulsion for
3 28 release except as provided in this division.
3 29 Information contained in the records of requests for
3 30 information from the database is privileged and
3 31 confidential, is not a public record, and is not
3 32 subject to discovery, subpoena, or other means of
3 33 legal compulsion for release except as provided in
3 34 this division. Information from the database shall
3 35 not be released, shared with an agency or institution,
3 36 or made public except as provided in this division.

3 37 4. Information collected for the database shall be
3 38 retained in the database for four years. The
3 39 information shall then be destroyed unless a law
3 40 enforcement agency or a governmental entity
3 41 responsible for the licensure, regulation, or
3 42 discipline of licensed health care professionals
3 43 authorized to prescribe or dispense drugs has
3 44 submitted a written request to the board or its
3 45 designee for retention of specific information in
3 46 accordance with rules adopted by the board under
3 47 section 124.510E.

3 48 5. A pharmacist or other dispenser making a report
3 49 to the database in good faith pursuant to this
3 50 division is immune from any liability, civil,
4 1 criminal, or administrative, which might otherwise be
4 2 incurred or imposed as a result of the report.

4 3 6. Nothing in this section shall require a
4 4 pharmacist or prescriber to obtain information about a
4 5 patient from the database. A pharmacist or prescriber

4 6 does not have a duty and shall not be held liable in
4 7 damages to any person in any civil or derivative
4 8 criminal or administrative action for injury, death,
4 9 or loss to person or property on the basis that the
4 10 pharmacist or prescriber did or did not seek or obtain
4 11 information from the database. A pharmacist or
4 12 prescriber acting in good faith is immune from any
4 13 civil, criminal, or administrative liability that
4 14 might otherwise be incurred or imposed for requesting
4 15 or receiving information from the database.

4 16 7. The board shall not charge a fee to a pharmacy,
4 17 pharmacist, or prescriber for the establishment,
4 18 maintenance, or administration of the database. The
4 19 board shall not charge a fee for the transmission of
4 20 data to the database nor for the receipt of
4 21 information from the database, except that the board
4 22 may charge a reasonable fee to an individual who
4 23 requests the individual's own database information or
4 24 to a person requesting statistical, aggregate, or
4 25 nonpersonally identified information from the
4 26 database. A fee charged pursuant to this subsection
4 27 shall not exceed the cost of providing the requested
4 28 information and shall be considered a repayment
4 29 receipt as defined in section 8.2.

4 30 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND
4 31 REFERRAL.

4 32 The board or its designee shall review the
4 33 information in the electronic drug database. If the
4 34 board determines, consistent with the board's
4 35 authority under this chapter or chapter 155A, that
4 36 there is probable cause to believe that drug diversion
4 37 or another violation of law may have occurred, the
4 38 board shall notify the appropriate law enforcement
4 39 agency or the governmental entity responsible for the
4 40 licensure, regulation, or discipline of the licensed
4 41 health care professional, and shall supply information
4 42 required to initiate an investigation. The board
4 43 shall not refer information relating to an individual
4 44 for further investigation except upon a probable cause
4 45 determination. A probable cause determination shall
4 46 be consistent with guidelines developed by the
4 47 advisory council established under section 124.510F.

4 48 Sec. 6. NEW SECTION. 124.510E RULES AND
4 49 REPORTING.

4 50 1. The board shall adopt rules in accordance with
5 1 chapter 17A to carry out the purposes of, and to
5 2 enforce the provisions of, this division. The rules
5 3 shall include but not be limited to the development of
5 4 procedures relating to:

5 5 a. Identifying each patient about whom information
5 6 is entered into the electronic drug database.

5 7 b. An electronic format for the submission of
5 8 information from pharmacies.

5 9 c. A waiver to submit information in another
5 10 format for a pharmacy unable to submit information
5 11 electronically.

5 12 d. Granting by the board of a request from a law
5 13 enforcement agency or a governmental entity
5 14 responsible for the licensure, regulation, or
5 15 discipline of licensed health care professionals
5 16 authorized to prescribe or dispense drugs for the
5 17 retention of information scheduled for deletion from
5 18 the database after four years when the information
5 19 pertains to an open investigation being conducted by
5 20 the agency or entity.

5 21 e. An application for an extension of time by a
5 22 pharmacy regarding information to be transmitted to
5 23 the board or its designee.

5 24 f. The submission by a person or governmental
5 25 entity to which the board is authorized to provide
5 26 information of a request for the information and a
5 27 procedure for the verification of the identity of the
5 28 requestor.

5 29 g. Use by the board of the database request
5 30 records required by section 124.510C, subsection 2, to
5 31 document and report statistics and law enforcement
5 32 outcomes and to identify inappropriate access or other
5 33 prohibited acts.

5 34 h. Submission of a request by an individual for
5 35 the individual's own database information and
5 36 verification of the identity of the requestor.

5 37 i. The development of a list of controlled
5 38 substances and other drugs that shall be included in
5 39 the database.

5 40 j. Access by a pharmacist or prescriber to
5 41 information in the database pursuant to a written
5 42 agreement with the board.

5 43 k. Terms and conditions of the contract, if the
5 44 board contracts for database administration with a
5 45 third-party or private vendor.

5 46 l. The correction or deletion of erroneous
5 47 information from the database.

5 48 2. No later than January 1, 2008, and every two
5 49 years thereafter, the board shall present to the
5 50 general assembly and the governor a report of the
6 1 following:

6 2 a. The cost to the state of implementing and
6 3 maintaining the database.

6 4 b. Information from pharmacies, prescribers, the
6 5 board, and others regarding the usefulness of the
6 6 database.

6 7 c. Information from pharmacies, prescribers, the
6 8 board, and others regarding the board's effectiveness
6 9 in providing information from the database.

6 10 d. Information documenting the timely transmission
6 11 of information from the electronic drug database to
6 12 authorized requestors.

6 13 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL
6 14 ESTABLISHED.

6 15 The board shall establish an advisory council to
6 16 provide oversight to the electronic drug database
6 17 program. The board shall adopt rules specifying the
6 18 duties and activities of the advisory council and
6 19 related matters.

6 20 1. The council shall consist of three licensed
6 21 pharmacists, three licensed physicians, two licensed
6 22 prescribers who are not physicians, and two members of
6 23 the general public. The board shall solicit
6 24 recommendations for health professional council
6 25 members from Iowa health professional licensing
6 26 boards, associations, and societies. The license of
6 27 each health professional appointed to and serving on
6 28 the advisory council shall be current and in good
6 29 standing with the professional's licensing board.

6 30 2. The council may make recommendations to advance
6 31 the goals of the database, which include
6 32 identification of misuse and diversion of identified
6 33 controlled substances and other drugs and enhancement
6 34 of the quality of health care delivery in this state.

6 35 3. Among other things, the council shall:

6 36 a. Assist the board in developing criteria for
6 37 granting requests by researchers and other persons for
6 38 statistical, aggregate, or nonpersonally identified
6 39 information using database information, developed
6 40 consistent with the goals of the database.

6 41 b. Assist the board in ensuring patient
6 42 confidentiality and the integrity of the patient's
6 43 treatment relationship with the patient's health care
6 44 provider.

6 45 c. Make recommendations regarding the continued
6 46 benefits of maintaining the electronic drug database
6 47 in relationship to cost and other burdens to the
6 48 board. The council's recommendations shall be
6 49 included in reports required by section 124.510E,
6 50 subsection 2.

7 1 4. Members of the advisory council shall be
7 2 eligible to request and receive actual expenses for
7 3 their duties as members of the advisory council,
7 4 subject to reimbursement limits imposed by the
7 5 department of administrative services, and shall also
7 6 be eligible to receive a per diem compensation as
7 7 provided in section 7E.6, subsection 1.

7 8 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS
7 9 AND PENALTIES.

7 10 The failure of a licensed pharmacist or licensed
7 11 prescriber to comply with the requirements of this
7 12 division, or the performance or causing the
7 13 performance of, or the aiding and abetting of another
7 14 person in the performance of, any of the prohibited
7 15 acts identified in this section shall constitute
7 16 grounds for disciplinary action against the pharmacist
7 17 or prescriber by the appropriate professional

7 18 licensing board. Each licensing board that licenses
7 19 prescribers and drug dispensers subject to the
7 20 provisions of this division may adopt rules in
7 21 accordance with chapter 17A to implement the
7 22 provisions of this section and may impose penalty as
7 23 allowed under section 272C.3. In addition, a civil
7 24 penalty not to exceed twenty-five thousand dollars for
7 25 each violation may be imposed.

7 26 1. A pharmacist who willfully and knowingly fails
7 27 to submit prescription information to the board or its
7 28 designee as required by this division, or who
7 29 knowingly and intentionally submits prescription
7 30 information known to the pharmacist to be false or
7 31 fraudulent, may be subject to disciplinary action by
7 32 the board.

7 33 2. A person authorized to access or receive
7 34 prescription information pursuant to this division who
7 35 willfully and knowingly discloses or attempts to
7 36 disclose such information with the intent to cause
7 37 harm to another person in violation of this division
7 38 is guilty of a class "D" felony.

7 39 3. A person who willfully and knowingly uses,
7 40 releases, publishes, or otherwise makes available to
7 41 another person any personally identifiable information
7 42 obtained from or contained in the database is guilty
7 43 of a serious misdemeanor.

7 44 4. A person without lawful authority who obtains
7 45 or attempts to obtain information, obtains or attempts
7 46 to obtain unauthorized access to, or who willfully and
7 47 knowingly alters or destroys valid information
7 48 contained in the database is guilty of a class "D"
7 49 felony.

7 50 5. A person authorized to access or receive
8 1 prescription information pursuant to this division who
8 2 knowingly and intentionally discloses confidential
8 3 information to a person who is not authorized to
8 4 receive the information pursuant to this division is
8 5 guilty of a serious misdemeanor.

8 6 6. This section shall not preclude a pharmacist or
8 7 prescriber who requests and receives information from
8 8 the database consistent with the requirements of this
8 9 chapter from otherwise lawfully providing that
8 10 information to any other person for medical or
8 11 pharmaceutical care purposes.>

8 12 #2. Page 12, by inserting after line 12 the
8 13 following:

8 14 <Sec. _____. EFFECTIVE DATE. The sections of this
8 15 Act relating to and establishing an electronic drug
8 16 database, being deemed of immediate importance, take
8 17 effect upon enactment.>

8 18 #3. Title page, by striking line 2, and inserting
8 19 the following: <providing for the creation of an
8 20 electronic drug database, establishing and
8 21 appropriating fees, providing penalties, and providing
8 22 an effective date.>

8 23 #4. By renumbering as necessary.

8 24

8 25

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8 27 _____
UPMEYER of Hancock

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8 31 _____
SMITH of Marshall

8 32 HF 833.502 81

8 33 rn/pj/117